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EXAMINER

KOHARSKI, CHRISTOPHER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## **DETAILED ACTION**

### ***Acknowledgements***

The Examiner acknowledges the reply filed 08/06/2009 in which claims 27, 45 and 50 were amended and new claims 51-52 were added. Currently claims 27-41, and 43-50 are pending for examination in this application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29, 32, and 43-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Svensson et al. (USPN5,098,397). Svensson et al. discloses percutaneous access device.

Regarding claims 27-29, 32, and 43-50, Svensson et al. discloses an implant (Figure 1) comprising: a port structure comprising an outer wall (surface near 8) having a substantially uniform outer circumference interrupted by a plurality of regions having areas of a smaller outer circumference (lip near 6, grooves near 9), wherein a first region of the plurality of regions comprises one or more discrete tactile surface structures (first region see below, single groove), and a second region (second region, lower multi-groove) of the plurality of regions comprises a plurality of discrete tactile surface structures (grooves of 9), wherein each of said discrete tactile surface structures encircles the port structure and are arranged along a length of the port body

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that comprises at least a portion of an implant area and are capable of being implanted subcutaneously, the plurality of discrete tactile surface structures (grooves near 9) improving ingrowth characteristics associated with the implant by promoting growth of cellular tissue in at least one direction relative to the surface of the implant; a holding structure (base structure) coupled to a first end of the port structure, the holding structure comprising an encircling ring (ring near 8) protruding from the first end of the port structure, the encircling ring comprising a plurality of openings spaced around said encircling ring; and a connecting structure (5) coupled to a second end of the port structure, the connecting structure protruding out of tissue when the implant is inserted into a body and capable of conditionally attaching to a connecting element (Figures 1-2).

Regarding claims 51-52, Svensson et al. further discloses a transcutaneous implant (Figures 1-2) comprising: a port structure (port near 8) comprising an outer wall (surfaces 7, 8 and bottom of 10) having a first region (top surface 7) and a second region (bottom surface near 10), each of the first and second regions having a substantially smooth surface, and a surface structure (grooves near 8 and 9) region disposed between the first and second regions, wherein the surface structure region comprises a plurality of discrete surface structures encircling the port structure and is arranged along a length of the port body that comprises at least a portion of an implant area (grooves near 8 and 9), the plurality of discrete surface structures being capable of improving ingrowth characteristics associated with the implant by promoting growth of cellular tissue in at least one direction relative to the surface of the implant; a holding

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structure (ring type structure near 9) coupled to a first end of the port structure (bottom terminal surface), the holding structure comprising an encircling ring (Figure 1) protruding from the first end of the port structure, the encircling ring comprising a plurality of openings (near 5, 8) spaced around said encircling ring; and a connecting structure (5) coupled to a second end of the port structure, the connecting structure protruding out of tissue when the implant is inserted into a body and capable of conditionally attaching to a connecting element (Figure 2), and wherein the holding structure further comprises an attachment region (bottom section attached near 1) configured for coupling the holding structure to the first end of the port structure, and wherein the attachment region includes a circumferential recess (opening in ring near 11, that port is in) in an outer surface thereof (Figures 1-2).

***Claim Rejections - 35 USC § 103***

Claims 31 and 33-41 are rejected under 35 U.S.C 103(a) as being unpatentable over Svensson et al. (USPN5,098,397).

Svensson et al. meets the claim limitations as described above except the specific tactile surface widths, depths and distance.

Regarding claim 28, lacking specific criticality, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Svensson et al. with the grooves as claimed by Applicant in order to improve tissue retention, and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

***Response to Arguments***

Applicant's arguments filed 08/06/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Svensson et al. (USPN5,098,397) reference does not disclose the discrete tactile surface structure being subcutaneous when the implant is inserted into the body and the reference does not disclose the specifics of the first and second regions smooth surfaces.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is the Examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the Svensson et al. (USPN5,098,397) reference discloses the invention as claimed by Applicant. Regarding the limitation of the surface structures being subcutaneous when implanted, the Examiner asserts this is a functional limitation and the port of Svensson et al. can be implanted to depth to which all of the surface structures are subcutaneous. Therefore the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Regarding the limitation of the smooth surface regions, the Examiner asserts the Svensson et al. reference meets the claimed limitations as disclosed and described above. The surfaces can be defined as the top and bottom surfaces of the port assembly and therefore contain the grooves between them.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 11/17/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763